Research Proposal Form of the Thesis Entitled

Knowledge, Attitude, Practices, and Perceived Barriers (KAP-B) towards the Tobacco Cessation Services in Mumbai metropolitan region, India: A descriptive study to assess the role of Pharmacists in Tobacco Cessation Services.

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By

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Introduction:

Worldwide tobacco usage is a community health concern, particularly in developing nations. According to World Health Organization (WHO), there are more than one billion current smokers worldwide and two third of them belongs to the low and middle-income countries.[1] Tobacco usage is becoming increasingly common in low and middle income countries whereas high income countries are showing a decline.[2] It is estimated that more than 70% tobacco usage will occur in developing countries worldwide by the year 2030.[3]

As far as the tobacco consumption is concerned, we rank 2nd in the world. A million people die from smoking-related causes in the nation each year, out of 100 million smokers. Studies have shown that 38% of Indian smokers attempt to quit tobacco every year but very few succeed. The quit rate (defined as former daily smokers among ever daily smokers) in India is shown to be 13% as compared to US which is almost 50%.[4,5]

Tobacco use causes major health inequalities around the globe. Tobacco usage is higher and quit rate is far from lass in deprived countries as compared to rest of the world.[5]
Even in developing countries , there exists a disparity.[6] Thus it is very important to focus on low-income communities and steps should be taken to outreach those tobacco users who would not otherwise meet the healthcare providers routinly.[7] situation in the India becomes more challenging because of the following reasons: limited resources, lack of healthcare professionals who are actively involved in tobacco cessation, lack of affordable pharmacotherapy and scarcity of research for effective tobacco cessation method for smokeless tobacco users.[8]

Previous studies have shown that even brief advice and referral from a health worker is a highly cost-effective method to reduce tobacco consumption in developed countries. However, there is a scarcity of evidence on the effectiveness of quit advice from low income countries and there are very limited studies which have assessed the effectiveness of brief advice on tobacco cessation for smokeless tobacco use. These shows an important research gap which require exploration.[9]

Pharmaceutical training involves counseling and educating patients. Pharmaceutical care has been defined as the “responsible provision of therapy for the purpose of achieving definite outcomes that improve the patient’s quality of life”.[10] Thus, the role of pharmacists in

smoking cessation may include dispensing over the counter NRT and other pharmaceutical smoking cessation aids as well as counseling patients.

There is growing evidence to support the role of pharmacists in providing expanded health services independently or as part of interprofessional teams. Given their accessibility and evidence supporting the effectiveness of cessation services delivered by pharmacists, community pharmacists can play a vital role in addressing tobacco use in Indian scenario.[10]

Since there are no such study available in India, current study will fill the evidence gap and will provide valuable information to explore the future role of pharmacists in tobacco cessation in India. Hence this study is planned to assess the knowledge , attitude, practices, and perceived barriers among pharmacists towards tobacco control services across Mumbai Metropolitan Region, India.

Review of literature:

1. **Sakka, S., Al-Shatanawi, T. N et al (2022)** [11]

They a study to assess the community pharmacists' knowledge, attitudes, and practice towards smoking cessation and identifying their perceived barriers for smoking cessation counselling utilizing a sample of community pharmacists in Northern Jordan. This was cross sectional questionnaire study with total 150 respondent. A structured English questionnaire, consisting of 5 parts, was used. The Survey assessed pharmacists' socio-demographics, knowledge, attitude, practice and perceived barriers related to tobacco use cessation services. Their mean age was 30.71±10.10 years. The mean of pharmacists' knowledge score was 3.74±0.38, while their positive and negative attitude were 3.87±0.43 and 3.18±0.66 respectively. Pharmacists' mean smoking cessation practice was 2.01+0.64. Barriers to providing cessation interventions included the lack of training on nicotine replacement therapy products (86%), the lack of smoking cessation programs (84%) and low demands from smokers (83.3%). : While knowledge related to tobacco use cessation services among the community pharmacists was sub-optimal, a good positive attitude and a low practice levels were observed. The lack of educational materials, low patients' demand, knowledge deficits, low training and the lack of cessation programs have been identified as barriers hindering the provision of smoking cessation services.

2. **Kurko, T., Linden, K. et al (2010)**[12]

conducted a study to study the National SC Guideline's familiarity and implementation in community pharmacies in Finland, as well as the variables associated with these aspects and

the supply of SC services.. A nationwide mail survey was sent to a systematic, sample of community pharmacy owners and staff pharmacists (total n = 2291). Response rate was 54% (n = 1190). Factors related to the SC Guideline familiarity were assessed by bivariate and multivariate analysis. Author found that almost half (47%) of the respondents (n = 1190) were familiar with the SC Guideline and familiarity enhanced Guideline implementation. The familiarity was associated with the respondents' perceptions of their personal SC skills and knowledge (OR 3.8); of customers' value of counseling on nicotine replacement therapy (NRT) (OR 3.3); and regular use of a pocket card supporting SC counseling (OR 3.0). Pharmacists' workplaces' characteristics, such as size and geographical location were not associated with familiarity. In addition to recommending NRT, the pharmacists familiar with the Guideline used more frequently other Guideline-based SC methods, such as recommended non-pharmacological SC aids, compared to unfamiliar respondents. Author concluded that SC Guideline familiarity and implementation is crucial for community pharmacists' involvement in SC actions in addition to selling NRT products. Pharmacists can constitute a potential public health resource in SC easily accessible throughout the country.

3. **Hilts, K. E., Corelli, R. L (2022)** [13]

conducted a study to explore pharmacists' perceptions of factors associated with the implementation of "Ask-Advise-Refer", a brief intervention approach that facilitates patient referrals to the tobacco quitline. It was a randomized controlled trials with 64 participants. Study measures, grounded in Rogers' Diffusion of Innovations Theory, assessed pharmacists' perceptions of implementation facilitators and barriers, perceptions of intervention materials provided, and perceived efforts and personal success in implementing Ask-Advise-Refer at 6-months follow-up. Findings indicated that while the brief intervention approach was not difficult to understand or implement, integration into normal workflows presents greater challenges and is associated with overall confidence and implementation success. Lack of time was the most significant barrier to routine implementation. Most (90.6%) believed that community pharmacies should be active in promoting tobacco quit lines. Based on findings, author recommended for development of systems-based approaches that lead to broad-scale adoption of brief interventions, including but not limited to tobacco cessation, in pharmacy settings.

4. **Goniewicz, M. L., Lingas, E. O (2010)** [14]

conducted a study to assess the role of Pharmacists in Smoking Cessation in Poland. It was a cross sectional questionnaire study where Surveys were administered in 2007–2008 to (a) current smokers, (b) members of a pharmacy association, and (c) pharmacy students in their

final year of training. Pharmacists were the highest ranked health professionals to whom Polish smokers reported they would turn for information about pharmacological support for smoking cessation. Most pharmacists (79%) reported their knowledge allowed them to provide basic smoking cessation information to their patients. Pharmacy students reported being more able to provide information about the health consequences of tobacco smoking than to help patients quit smoking (85% vs. 61%). Study recommended that To extend and promote smoking cessation efforts, comprehensive tobacco cessation training should be a required component of the pharmacy school curriculum.

5. **Darker, C. D., Burke, E (2022)**[15]

Smoking poses a serious risk of early preventable death and disease especially for women living with socio-economic disadvantage (SED). A smoking cessation programme, 'We Can Quit', was developed in Ireland tailored to SED women. This includes group-based support delivered by trained lay local community facilitators (CFs) and free nicotine replacement therapy (NRT). The intervention was pilot tested in a cluster randomized controlled trial, 'We Can Quit 2'. It embedded qualitative design using the UK Medical Research Council's process evaluation framework. Semi-structured interviews with trial participants (N=21) and CFs (N=8). Thematic analysis was utilized. Peer-modelling, a non-judgmental environment, CFs facilitation of group support were viewed as acceptable program related factors. Some participants expressed concerns about NRT side efects. Provision of free NRT was welcomed and accepted by participants, although structural barriers made access challenging. Pharmacists took on a role that became larger than originally envisaged – and the majority provided additional support to women in their quit attempts between group meetings which augmented and supplemented the intervention sessions provided by the CFs. Participants reported good acceptance of repeated measures for data collection, but mixed acceptability of provision of saliva samples. Low literacy affected the feasibility of some women to fully engage with program and trial-related materials. This was despite efforts made by intervention developers and the trial team to make materials (e.g., participant intervention booklet; consent forms and participant information leaflets) accessible while also meeting requirements under 2018 European General Data Protection Regulation legislation. Hypothetical scenarios of direct (e.g., researcher present during program delivery) and indirect (e.g., audio recordings of programme sessions) observational fidelity assessments for a future definitive trial (DT) were acceptable. Study highlighted the important role a community pharmacists can play in cessation services.

6. **Hartman-Filson, M., Chen, J et al (2022)** [16]

assessed a community-based, single-arm uncontrolled trial of a pharmacy-linked intervention for smoking cessation for persons experiencing homelessness (PEH). Here shelter staff were trained on how to provide brief cessation counseling, then tested a program among PEH in two shelters that included one-time pharmacist-delivered cessation counseling and nicotine replacement therapy (NRT) for 3 months. Study examined factors associated with cigarette consumption and quit attempts. Of the 52 participants, 71% were male and 49% were Black. The majority of participants reported making a quit attempt (70%) and using NRT (84%). Having an encounter with staff in the past week was associated with a 40% reduction in weekly consumption (Incidence rate ratio (IRR) 0.61, 95% CI 0.57-0.67) and using medications in the past week was associated with a 23% reduction in weekly consumption (IRR 0.78, 95% CI 0.75-0.81). Using medications in the past week increased the odds of a quit attempt 2.89 times compared to not using medications (Adjusted odds ratio (AOR), 2.89, 95% CI 1.45-5.77). Findings highlighted a role for leveraging community-based pharmacists to expand smoking cessation services in homeless shelters to reduce tobacco use among PEH.

7. **Gong, J., Baker, C. L et al (2016)** [17]

conducted a study to evaluate an enhanced pharmacy care (EPC) program involving personalized pharmacist-provided telephone counseling for supporting prescription smoking cessation medications compared with usual care (UC). Cigarette smokers filling a newly prescribed smoking cessation pharmacotherapy and with pharmacy benefits managed by Express Scripts were recruited. Qualified subjects were randomized 1:1 to EPC and UC. Subjects in EPC received 3 telephone-counseling sessions from specialist pharmacists during the early course of the study, while subjects in UC did not receive any counseling sessions. he primary outcome assessed the 1-week point prevalence (PP) of smoking abstinence at the end of the trial (week 12). Secondary outcomes included 4-week PP at week 12 and adherence, evaluated by proportion of days covered (PDC), to prescribed smoking cessation pharmacotherapies. here were 1,017 randomized subjects. Among them, 1,002 subjects were included in the analysis, and 513 were randomized into EPC and 489 into UC. Varenicline and nicotine replacement therapy (NRT) were most frequently prescribed for smoking cessation. In EPC, 46.0% received all 3 counseling sessions; 29.4% received 2 sessions; and 14.6% received 1 session. Overall, 353 subjects in EPC and 383 subjects in UC completed the week 12 assessment. Adherence to prescription smoking cessation medication was

significantly higher in EPC versus UC (49.7% vs. 45.6%; P = 0.033). This study suggested that smokers may be benefited by an enhanced tobacco cessation program.

8. **Patwardhan, P. D., & Chewning, B. A. (2012)** [18]

conducted a study to test the feasibility of implementing ask-advise-refer (AAR) in representative community chain pharmacies serving low socioeconomic areas, and to assess the effectiveness of a multimodal intervention on short-term implementation of AAR. It was a Randomized controlled trial at Sixteen community chain pharmacies in South-central Wisconsin. A multimodal intervention including: 1) training to implement AAR, 2) workflow integration recommendations, 3) a cessation poster to create awareness, and 4) a support visit conducted. Main outcome measures were number of patrons asked about their tobacco use, number of tobacco users advised to quit, number of quitline cards given, and number of tobacco users enrolled in the quitline. As hypothesized, the multimodal intervention significantly predicted the number of patrons asked (estimate=4.84, incidence rate ratios[IRR]=127.2; p<0.001). This trial demonstrated the feasibility of implementing AAR in routine community pharmacy practice. This trial also indicates the short-term effectiveness of the intervention in facilitating AAR, implementation in partnership with other public health services and systems.

9. **L. A., Harris, K. J., & Noonan, C. W. (2009)** [19]

conducted a study to assess the effectiveness on smoking cessation of a face-to-face group program conducted by the pharmacist team compared with a brief standard care session delivered by a pharmacist over the telephone. An open-label, prospective, randomized, controlled trial was conducted at a Veterans Health Administration, community-based outpatient clinic in the Rocky Mountain region. Participants were randomly assigned to receive a 3-session face-to-face group program conducted by the pharmacist team or one 5- to 10-minute standard care session delivered by the pharmacist team over the telephone. Participants in both groups were offered either immediate-release bupropion or nicotine patch at no cost. The primary outcome of self-reported abstinence was biochemically confirmed by urinary cotinine at 6 months after the quit date. Using intent-to-treat procedures, confirmed abstinence rates at the end of 6 months were 28% in the pharmacist-delivered face-to-face treatment group and 11.8% in the standard care telephone session control group (p < 0.041). This study demonstrated that pharmacists are effective providers of tobacco cessation interventions. Greater utilization of pharmacists in tobacco cessation efforts could have a significant impact on smoking rates, prevention of tobacco-related diseases, and overall improvement in public health across the US.

10. **Hudmon, K. S., Corelli, R. L et al (2018)** [20]

A randomized controlled trials were conducted to evaluate the long-term impact of pharmacy personnel (pharmacists, technicians) in referring patients who want to quit smoking to the tobacco quitline. Two intervention approached that is academic detailing (AD) and mailed quitline materials (MM) were compared in the study. Study involved Community pharmacies in Connecticut (n=32) and community pharmacists from Washington (n=32). Follow up was done at 6 months and 12 months and comparison about increase in percentage of Quitline registrants from the baseline was done. Study found the increase in the percentage of quitline callers from 2.2% to 3.8% in 12 months follow up period which was statistically significant at p=0.001. Around 10,013 quitline cards and 4,755 brochures were distributed across 64 pharmacies. However the number of registrants who reported hearing about the quitline from a pharmacy did not differ by intervention approach (AD versus MM). study concluded that involving community pharmacists in tobacco cessation would increase the opportunity to promote the use of Quitline among the tobacco users.

Research problem:

What is the knowledge, attitude, practices, and perceived barriers of pharmacists (KAP-B) towards tobacco cessation in Mumbai metropolitan region, India?

Significance/ importance:

The Global Adult Tobacco Survey (GATS 2017) [21] has revealed that over 55% smokers and 50% of smokeless tobacco users in India want to quit the habit but have been unsuccessful.

The reason behind this failure may be due to the insufficient health workers who can be involved in tobacco cessation program.

Along with having the necessary expertise, a qualified professional who can assist someone in quitting smoking also needs to be a positive role model who has a positive approach towards quitting. The WHO emphasizes the role of varied health care professionals like physicians, dentists, nurses, pharmacists and various health related organizations in tobacco cessation and reducing tobacco consumption. [22]

The role of pharmacists towards tobacco control and their knowledge, attitude and current practices has never explored in India. It is expected that the findings will provide baseline data regarding pharmacists' knowledge, attitudes, and practices as well as point out elements that are expected to motivate community pharmacists to participate in Tobacco control services.

Research objectives:

- To assess the knowledge related to various aspects of tobacco cessation among pharmacists in Mumbai Metropolitan Region, India
- To assess the attitude related to various aspects of tobacco cessation among pharmacists in Mumbai Metropolitan Region, India
- To assess the practices related to the tobacco cessation among pharmacists in Mumbai Metropolitan Region, India
- To assess the perceived barriers related to various aspects of tobacco cessation among pharmacists in Mumbai Metropolitan Region, India
- To correlate knowledge, attitude , practices, and perceived barriers with various sociodemographic variables.

Research Methodology:

Study design: It is a questionnaire based descriptive cross-sectional study

Ethical approval: It will be taken from Institutional Ethics Committee before start of the study

Inclusion criteria:

1. Pharmacists with B Pharm or D Pharm or master's degree.
2. Pharmacists who are willing to participate and give consent.
3. All pharmacies which are registered under Maharashtra State Pharmacy Council. (MSPC Online Portal (mspcindia.org))

Exclusion Criteria:

1. Conditions which do not meet above said inclusion criteria will be excluded.

Study setting: Data will be collected at individual pharmacy across Mumbai Metropolitan region, India

Sample size and Sampling method: Sample size will be determined based on the results of pilot study by using G power software. Lists of registered pharmacies will be obtained from BMC and NMMC official website and stratified random sampling will be used to select the pharmacies in each ward according to geographical location.

Study Instrument (Questionnaire):

A English language structured questionnaire will be developed. It will include five domains: general aspects, knowledge, attitudes, practice, and perceived barriers (KAP&B) pertaining to tobacco cessation. The questionnaire will be developed based on previous studies,[11,14,18] referring to the existing literature and consulting expert in the field. Information about Age, Gender, academic degree, years of experience, pharmacy description, pharmacy location, pharmacist tobacco use status, number of pharmacists, number of assistants, tobacco control programs attended, NRT products which are available at the pharmacy, and customers request to support to quit tobacco will be sought. In knowledge sections (11 questions), questions pertaining to NRT in general and usage of nicotine gums and patches will be asked. Responses will be recorded as : Yes/ No/ I don't know format.

The section concerning attitude (10 questions) will have a total of ten statements utilizing the Likert scale. 1 (Strongly disagree), 2 (Disagree), 3 (Neutral) 4 (Agree) and 5 (Strongly agree). Participants' practice will be scored according to their answers on a scale of; 1 (Never), 2 (Seldom), 3 (Sometimes), 4 (Usually) and 5 (Always). A total of six questions will be included in practice section. Pharmacists will be asked to identify potential hurdles in offering TC counselling at the pharmacy. Their responses will be recorded by marking each one with a "Yes" or "No." This section will have a total of eight questions. The questionnaire will be subjected to reliability and validity testing before finalization. Chron Bach's alpha coefficient and Cohen's Kappa values will be calculated for the assessment of validity and reliability. [23] Questionnaires will be distributed to the pharmacists and collected immediately upon completion.

Data Analysis:

Data will be analyzed by using Statistical Package for Social Sciences (SPSS) for Windows, Version 17.0. Chicago. Data will be entered in Microsoft Excel spread sheet and would be subjected to statistical analysis. Descriptive data including demographic details, responses to the knowledge, attitude , practices, and barriers will be presented with percentages or means and standard deviation (sd). Mean knowledge attitude and practice scores will be calculated. These scores will be compared with basic and demographic details. Kolmogorov-Smirnov test or Shapiro-Wilk test will be used to check the normality of the data. Based on the results parametric or non- parametric tests will be applied to compare and associate different

variables in the study. One-way ANOVA and the t-test will be used to compare the mean scores for parametric analysis and Mann Whitney u test and Kruskal-Wallis test will be used for non parametric analysis. The Pearson correlation coefficient or Spearman's Rank Correlation coefficient will be used to examine the correlation between the means of knowledge, attitude, and practice. Logistic Regression analysis will be used to identify various factors which are playing major roles in pharmacists' tobacco cessation behavior. P value with a 95% confidence interval will be set at 0.05 to indicate significance.

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